

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In Re PHARMACEUTICAL INDUSTRY)
 AVERAGE WHOLESAL PRICE)
 LITIGATION)

MDL No. 1456
Civil Action No.: 01-12257-PBS

THIS DOCUMENT RELATES TO THE)
AMENDED MASTER CONSOLIDATED)
CLASS ACTION)

Hon. Patti Saris

Chief Mag. Judge Marianne B.
Bowler

**MEMORANDUM IN OPPOSITION TO AVENTIS' MOTION
TO COMPEL AND IN SUPPORT OF UNITED STATES'
CROSS-MOTION TO QUASH SUBPOENA OF NHIC EMPLOYEE**

On or about October 28, 2005, Aventis Pharmaceuticals, Inc., on behalf of all defendants (Defendants) to the Amended Master Consolidated Class Action Complaint, served on National Heritage Insurance Company (NHIC), a deposition subpoena that had been issued by this Court.¹ The Centers for Medicare & Medicaid Services (CMS) is the component of the Department of Health & Human Services (HHS) responsible for administering the Medicare program. NHIC is a Medicare carrier by contract with CMS. A Medicare carrier processes claims for services including doctors visits, outpatient care and drugs covered under Medicare Part B. The deposition testimony sought by the defendants relates to NHIC's actions and contractual responsibilities as a Medicare carrier. The employee of NHIC who would provide such testimony is considered an HHS employee and is covered by the agency's "Touhy regulations," 45 C.F. R. Part 2, which set forth a procedure that must be followed whenever a litigant in a case

¹ The subpoena sought both testimony and production of records. The government's position is that the subpoena for records will be complied with to the extent that records are not privileged or otherwise protected from disclosure.

in which the United States is not a party wishes to depose a HHS employee about information that the employee acquired in the course of performing the employee's official duties.² Here, the Defendants have not complied with these regulations, and have instead moved to compel an NHIC employee's deposition. Therefore, the United States respectfully asks this Court to deny Defendants' motion, and quash the subpoena for testimony that was issued to NHIC, in accordance with Fed. R. Civ. P. 45(c)(3). Further, the United States respectfully asks this Court to deny Defendants' Motion to Compel production of records.

BACKGROUND

I. The HHS TOUHY REGULATIONS

The HHS Touhy regulations govern situations where testimony of a current or former HHS employee is sought in connection with a lawsuit in which the United States is not a party, if that testimony (1) involves information acquired in the course of the former employee's official duties, or (2) is sought because of the person's official position at HHS. 45 C.F.R. § 2.1. Specifically, 45 C.F.R. § 2.3 states:

No employee or former employee of [HHS] may provide testimony . . . in any proceedings to which this part applies concerning information acquired in the course of performing official duties or because of the person's official relationship with the Department unless authorized by the Agency head pursuant to this part based on a determination by the Agency head, after consultation with the Office of the General Counsel, that compliance with the request would promote the objectives of the Department.

For the purpose of the HHS Touhy regulations an employee includes

any employees of health insurance intermediaries and carriers performing functions under agreements entered into pursuant to sections 1816 and 1842 of the Social Security Act, 42 U.S.C. 1395h and 1395u.

² Touhy regulations are named after a Supreme Court case that recognized the authority of agency heads to restrict the release of information by agency employees, United States ex rel. Touhy v. Ragen, 340 U.S. 462 (1951).

45 C.F.R. § 2.2. The regulations further provide that all requests for covered testimony “must be addressed to the Agency head in writing and must state the nature of the requested testimony, why the information sought is unavailable by any other means, and the reasons why the testimony would be in the interest of [HHS] or the federal government.” 45 C.F.R. § 2.4.

These regulations are consistent with similar regulations that have been issued by most other federal agencies.³ Promulgation of such regulations is authorized by 5 U.S.C. § 301, which permits agency heads to regulate the governance of their departments, and has been approved by the Supreme Court in United States ex rel. Touhy v. Ragen, 340 U.S. 462 (1951). It is well established that when an agency has enacted valid Touhy regulations, litigants may not subpoena or request testimony of covered persons without complying with those regulations.⁴ If the agency denies the litigant’s request, that decision may be reviewed under the Administrative Procedure Act under an “arbitrary and capricious” standard. Houston Business Journal, 86 F.3d at 1212, n. 4; Bobreski, 284 F.Supp.2d at 73-74; see also Truex v. Allstate Ins. Co., 2006 WL

³ *See e.g.* 28 C.F.R. §§ 16.21(a), 16.22(a), 16.28 (Department of Justice); 32 C.F.R. § 97.3(b) (Department of Defense); 22 C.F.R. Part 72, § 172.5 (Department of State); 32 C.F.R. Part 1905 (Central Intelligence Agency); 12 C.F.R. § 4.32(b)(v) (Office of the Comptroller of Currency); 10 C.F.R. § 202.22 (Department of Energy); 49 C.F.R. § 9.3 (Department of Transportation); 5 C.F.R. § 2502.31 (Executive Office of the President, Office of Administration).

⁴ Houston Business Journal, Inc. v. Office of the Comptroller of Currency, 86 F.3d 1208, 1212, n. 4 (D.C. Cir. 1996); Ho v. United States, 374 F. Supp.2d 82, 83 (D.D.C. 2005); Bobreski v. U.S. Environmental Protection Agency, 284 F. Supp.2d 67, 73-74 (D.D.C. 2003); *see also Owens v. Republic of Sudan*, 374 F. Supp.2d 1, 28-29 (D.D.C. 2005) (requiring federal litigant to comply with applicable Touhy regulations); In re S.E.C. ex rel. Glotzer, 374 F.3d 184, 192 (2d Cir. 2004) (a party seeking judicial review of an agency’s non-compliance with a subpoena must first exhaust its administrative remedies); Smith v. Cromer, 159 F.3d 875 (4th Cir. 1998), *cert denied* 528 U.S. 826 (1999) (enforcing Department of Justice Touhy regulations); Edwards v. U. S. Dept. of Justice, 43 F.3d 312, 317 (7th Cir. 1994) (a federal employee cannot be compelled to obey a subpoena issued in violation of valid Touhy regulations).

241228, *4 (D.D.C. Jan. 26, 2006) (motion to quash subpoena granted because litigant failed to exhaust APA remedies prior to filing motion to compel).

II. FACTUAL BACKGROUND

The deposition at issue here is being sought in connection with In re: Pharmaceutical Industry Average Wholesale Price Litigation, Case No. 01-12257-PBS (D. Mass.), a class action alleging that certain pharmaceutical companies fraudulently overstated the published average wholesale price (AWP) of many of their prescription drugs. It is alleged that overstating the AWP results in inflated payments for such drugs by beneficiaries of the federal Medicare Part B program, private health and welfare plans and other end-payors. The Defendants' primary defense appears to be that the government knew of the widespread pricing and reporting practice and has acquiesced in Defendants' practices with respect to AWP.

Significantly, the United States is not a party to the AWP MDL. Nevertheless, the government has cooperated in responding to previous subpoenas issued by the defendants by producing voluminous documentation, numbering in the tens of thousands of pages, and incurring several hundred thousand dollars in production costs. HHS has previously produced documents from its Medicare Part B carriers, including NHIC, all of its regional offices and its CMS Central Office location in Baltimore. See Exhibit A.

On October 28, 2005, Defendants served an additional subpoena on NHIC for both testimony and records related to NHIC's role as a Medicare Part B carrier. See Exhibit B. In discussions between NHIC and Defendants, NHIC pointed out that it had previously produced a voluminous number of documents. NHIC believed the current subpoena would be withdrawn following a review of already produced documents. However, approximately two months later Defendants pursued a response from NHIC. Although NHIC and the Defendants were able to

narrow the scope of the additional records they sought, NHIC was obliged to seek guidance from CMS as to the propriety of producing records and data NHIC generated while carrying out its Medicare carrier contractual responsibilities. In addition, NHIC was concerned that the documents contained personal patient health information. NHIC is still working with CMS to address those concerns. Finally, a production of documents on the scale that Defendants have requested, including the review of 121 boxes of pre-1997 documents kept offsite, will be costly and time consuming. As Defendants are aware, documents identified by NHIC will have to be reviewed by the government for privilege and other like issues. In the government's last large scale production of documents to defendants in the AWP MDL this process took several months. The government has yet to be paid the hundreds of thousands of dollars it is owed for that production. That said, the government will work with NHIC to produce those records which are responsive to Defendants' requests.

In the meantime, the Defendants have continued to insist that they require live testimony from an NHIC employee. Because Defendants have not voluntarily dropped their request for live testimony, the government responded by providing a letter, dated March 8, 2006, which sets out the HHS Touhy regulations which are required to be complied with before the government will consider a request for an employee to testify in a litigation matter to which the government is not a party. See Exhibit C. To date, the defendants have not withdrawn their subpoena for testimony and have not complied with HHS' Touhy regulations.

The policies and practices to which an NHIC employee might be able to testify are related to NHIC's business as a Medicare Part B carrier. Specifically, Defendants have indicated they are interested in an NHIC employee who can testify in the areas of Medicare Part B pricing and Medicare Part B claims management. The government asserts that such policies and

practices are evidenced by the voluminous documentation already produced to Defendants in this litigation. That documentation includes, but is not limited to, carrier and central office correspondence concerning the use of average wholesale price, studies which analyze the use of average wholesale price for the purpose of reimbursement and information on how each carrier priced drugs prior to the government's use of one carrier to centralize pricing. To the extent defendants assert they require additional documentation from the government or its agents, including Medicare Part B carriers, the government will work with the defendants to expedite the review and production of such documents.

ARGUMENT

There is no dispute that the HHS Touhy regulations, on their face, set forth the exclusive procedure that must be followed whenever a litigant in a case in which the United States is not a party seeks the testimony of an agency employee about information obtained in the course of his or her official duties. There is also no question that Defendants have refused to follow that procedure here. Despite the fact that defendants are clearly seeking to depose an employee of NHIC about and because of his or her position with NHIC as a Medicare Part B carrier, they did not submit a Touhy request to HHS, and have not exhausted their administrative remedies. Defendants' motion to compel should be denied as premature, since it is well established that one must exhaust one's administrative remedies in accordance with the Administrative Procedure Act before challenging the validity of a Touhy regulation in court. Even if Defendants' motion to compel were otherwise ripe, however, its subpoena should be quashed because the HHS Touhy regulations are valid and enforceable as applied to agency employees, which includes employees of a Medicare carrier.

I. DEFENDANTS' FAILED TO EXHAUST THEIR ADMINISTRATIVE REMEDIES

Under the Administrative Procedure Act, litigants who wish to challenge an agency's Touhy regulations are required to submit a request for information to the agency, see if that request is denied, and then file an appeal. The appeal can challenge the validity of the regulation, the agency's application of the regulation to the specific facts at issue, or both. Defendants' motion to compel improperly seeks to evade this exhaustion requirement. *See In re S.E.C. ex rel. Glotzer*, 374 F.3d 184, 188-89, 192 (2d Cir. 2004) (when defendant had failed to exhaust administrative remedies, appellate court grants mandamus writ to vacate district court order compelling SEC employees to give testimony); *In re Boeh*, 25 F.3d 761, 764 (9th Cir. 1994), *cert. denied* 513 U.S. 1109 (1995) ("plaintiffs selected an improper method of attempting to compel Boeh's testimony."); *Truex v. Allstate Ins. Co.*, 2006 WL 241228, *4 (D.D.C. Jan. 26, 2006) (court grants motion to quash deposition subpoena for FEMA employee for failure to exhaust administrative remedies); *Golden Pacific Bancorp v. FDIC*, Case No. CIV A 99-3799(JCL), 1999 WL 1332312 (D.N.J. 1999).

On their face, the HHS regulations apply to Defendants' subpoena. Under these circumstances, Defendants' were required to follow the regulation and exhaust its administrative remedies before bringing the issue to this Court. By requiring litigants seeking government information to exhaust their administrative remedies in accordance with the Administrative Procedure Act, Touhy regulations give the Government the opportunity to moot any controversy by granting the requests for information, either in whole or in part. Even if a request is denied, the process of exhausting administrative remedies creates a more complete record for the district court to evaluate. This is true regardless of whether the testimony being sought is from a current

or former Government employee or an employee of a Medicare carrier. As the court stated in

Golden Pacific Bancorp:

The exhaustion doctrine serves the salutary interests of judicial economy, by offering an agency the opportunity to correct errors, moot a controversy, or develop an administrative record, and separation of powers, by assuring that courts do not unduly intrude into the operations of executive branch administrative agencies.

Golden Pacific Bancorp v. FDIC, 1999 WL 1332312 at *2; *also* DRG Funding Corp. v.

Secretary of Housing and Urban Development, 76 F.3d 1212, 1214 (D.C. Cir. 1996), *rehearing denied*, 83 F.3d 1482 (1996) (APA exhaustion requirement “allows the agency an opportunity to apply its expertise and correct its mistakes, it avoids disrupting the agency’s processes, and it relieves the courts from having to engage in ‘piecemeal review which is at the least inefficient and upon completion of the agency process might prove to have been unnecessary.’”) (citations omitted).

Here, by failing to exhaust its administrative remedies, Defendants have deprived the Government of an opportunity to moot or narrow the controversy before this Court, and have prevented the Government from developing a factual record concerning the extent to which Defendants are seeking information that is privileged or protected, or in this matter, is readily accessible through documents already produced. The Government respectfully submits that Defendants’ motion to compel should be denied as premature due to Defendants’ failure to exhaust its administrative remedies.

CONCLUSION

For the reasons set forth above, the United States respectfully asks this Court to deny Defendants' motion to compel the deposition of an employee of NHIC and produce records, and to grant the Government's cross-motion to quash that deposition.

DATED: March 17, 2006

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, George B. Henderson, II, hereby certify that on this date I caused copies of the foregoing document to be served upon counsel for each party by electronic transmission through the ECF system to the registered participants as identified on the Notice of Electronic Filing (NEF).

March 17, 2006

/s/ George B. Henderson, II
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